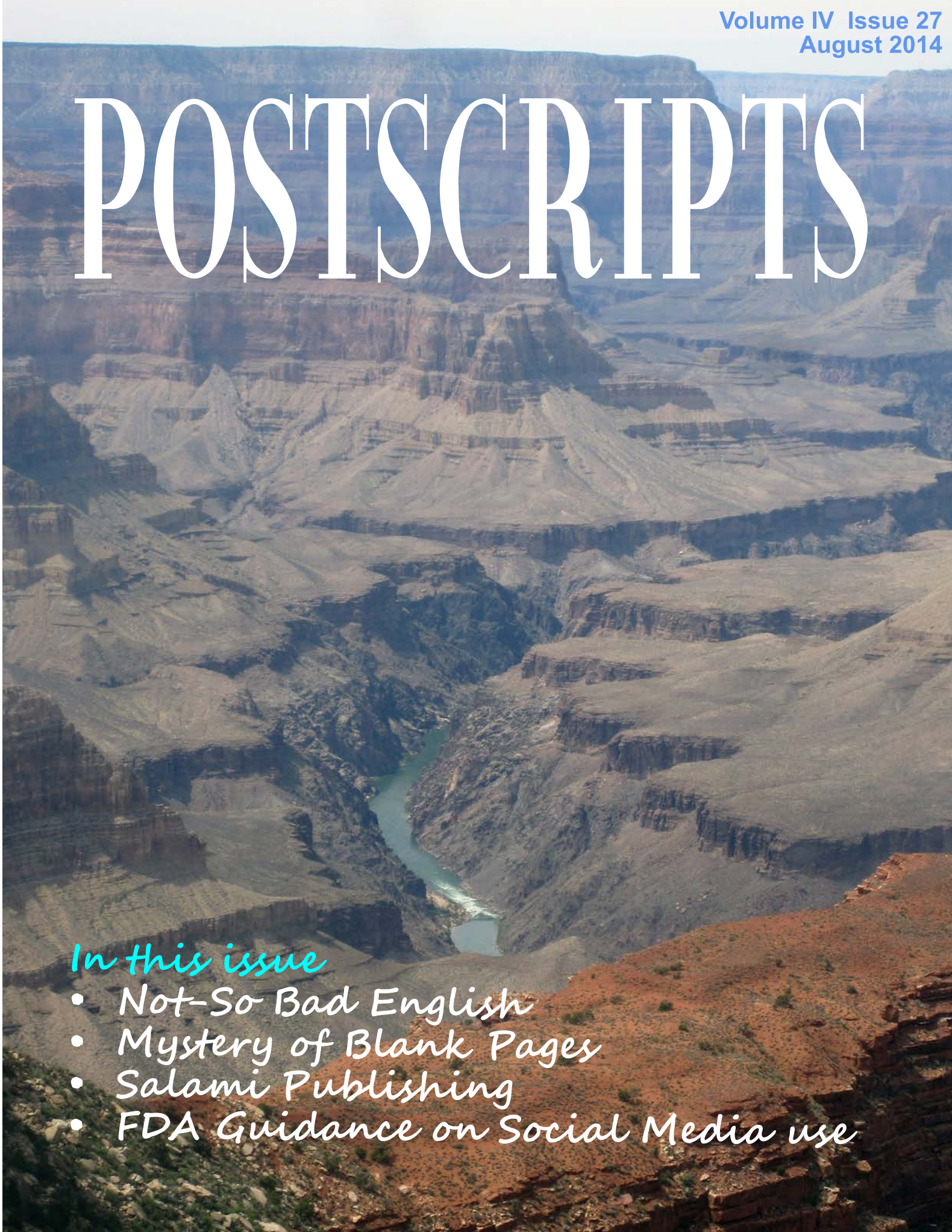
Volume IV Issue 27
August 2014

POSTSCRIPTS



In this issue

Official publication of the American Medical Writers Association Pacific-Southwest Chapter

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

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Postscripts Website:
http://issuu.com/postscripts

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www.amwa-pacsw.org

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SUBSCRIPTION

Postscripts is published monthly except in January and July. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month.

INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

American Medical Writers Association
Pacific Southwest Chapter
(AMWA Pac-SW)
San Diego, CA
www.amwa-pacsw.org

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POSTSCRIPTS

August 2014 | Volume 4, No. 27

in this issue. . .

EVENTS AND NOTICES

August 9, 2014, Saturday: AMWA-SDRAN Joint Meeting.
To register for the meeting, go to the SDRAN website Events Page at:
http://www.sdran.org/#!events-and-seminars

CANCELLED

CHAPTER CONTACTS

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Asilomar Conference Chairs: Jacqueline A Dyck-Jones, PhD, MSc & Jennifer Grodberg, PhD, RAC

COVER: Colorado River, South Rim, Grand Canyon. By Michele Mathieu, AMWA PacSW member.

From the President's Desk

"August rushes by like desert rainfall,
A flood of frenzied upheaval,
Expected,
But still catching me unprepared.
Like a match flame
Bursting on the scene,
Heat and haze of crimson sunsets.
Like a dream
Of moon and dark barely recalled,
A moment,
Shadows caught in a blink.
Like a quick kiss;
One wishes for more
But it suddenly turns to leave,
Dragging summer away."

— Elizabeth Maua Taylor

Hi everyone,

Are you enjoying your Summer? Did you get a chance to add Lanie Adamson's story from the July newsletter to your Summer reading list? Many thanks to Lanie, Ajay and all who contributed to make this such a special newsletter. Please spend some time reading this poignant story about one of our fellow medical writer's journey. This newsletter and our past newsletters are available at http://issuu.com/postscripts.

It was nice to meet many of you at the Drug Information Association (DIA) June Medical Writer meet-up. We had a great time at the Tin Fish in the gaslamp district. More events are being planned 'so stay tuned!'

It's hard to believe that 'selfie' has been added to the dictionary but Rebecca J. Anderson provides us with an update about what words we can expect to see in the future. Thank you to our Past-President, Secretary and Treasurer Noelle Demas for providing a summary about her interactions at the July Executive Committee meeting. Wim D'Haeze and Sally Altman always do a great job keeping us updated about what is happening in European and US regulatory news.

Ever have issues with blank pages? Susan Chang gives us some tips on how to handle blank pages when working with new documents. Thank you to Dikran Toroser for his review of duplicate publications, Ellen Klepack for the pharmacovigilance updates and Irene Yau for keeping us updated about job postings.

To end our newsletter, Michele Mathieu and Deborah Brown shared some of their Summertime travel pictures of the Grand Canyon, Sedona and Big Sky. If you wish to contribute to our newsletter, please contact our star Editor, Ajay K Malik (ajay@amwa-pacsw.org).

We like being active so please let us know if you would like to help plan an AMWA Pacific Southwest Chapter event in your area.

Enjoy the rest of the Summer!

Donna

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter

AMWA Pacific-Southwest Chapter warmly welcomes our new members

Alayna Mackay – San Diego, CA

Angela Tetmeyer Yazici – La Jolla, CA

Jessica Fowler – Los Angeles, CA

Osnat Ben-Shahar – Goleta, CA

Salil Sheth – Diamond Bar, CA

Beach By JessicaCooper1231 (www.morguefile.com/creative/JessicaCooper1231). Image URL: http://mrg.bz/U0Q6uA

List courtesy of Gail Flores, PhD, AMWA-PacSW membership coordinator.

An Informative and Fun Gathering with the Executive Committee

By Noelle Demas, MS
Past-President, AMWA PacSW chapter (2009-2011)

As the Annual Conference Administrator for the 2015 Conference, I joined the AMWA Executive Committee (EC) in Columbus, Ohio for the summer EC meeting on July 17 and 18, 2014. The EC is made up of the National officers (President, President-Elect, Secretary, and Treasurer), the Executive Director along with key headquarters staff members, and the Administrative Department leaders for the various areas of interest for AMWA for the year (eg, Certification Commission, Annual Conference, Chapter Relations, etc.). Over the two days, I enjoyed witnessing and being a part of the camaraderie and collaboration as the dedicated EC members discussed various AMWA business items along with some wittily interspersed humor. It was amazing to gain the understanding about how much these members care about the organization and want to help it grow and meet the members' needs. I especially liked getting to know the EC members at breakfast, lunch, and dinner.

This was my first EC meeting as I prepare to officially join the EC at the 74th Annual Conference in Memphis, TN. I look forward to a fun and productive time on the EC; leading the annual conference planning and participating in the various discussions in other areas of our great organization.

Not-So Bad English

By Rebecca J. Anderson, PhD

The *Merriam-Webster Collegiate Dictionary* recently updated its listings and added about 150 new words, including: hashtag, selfie, big data, and turducken[1]. Today, those words are part of everyone's vocabulary, but ten years ago, they were as foreign as poutine[2]. Non-native speakers habitually complain that English is one of the hardest languages to learn, because the words have so many shades of meaning. (My Thesaurus is more dog-eared than my dictionary.) And then we throw in turducken. Can you blame them?

On top of that, there is definition-creep (and also creepy definitions, but that's another story). In our grandparent's day, a calculator was a person who performed calculations. Now it's an app on your iPhone—two more words your grandparents probably didn't know. Ammon Shea has a lot of fun explaining all of this in *Bad English: A History of Linguistic Aggravation*—aggravation that makes a professional writer's fingers curl. When we joined the fraternity, we all put our hands on the dictionary and swore to use each word's official definition, the whole definition, and nothing but the definition. We cringe when "literally," "decimate," "unique," and "irregardless" are misused.

Take, for example, "unique." Like me, you probably continue to follow the rule published in 1906 by the Fowler brothers in *The King's English* that "A thing is unique, or not unique; there are no degrees of uniqueness." However, Shea explains that the dictionary gurus are caving, and the meaning has been broadened. The *New Oxford American Dictionary* defines it as "particularly remarkable, special, or unusual." *Merriam-Webster's Collegiate Dictionary* also includes "unusual" among the definitions, and *The American Heritage Dictionary* says the word means "remarkable; extraordinary."

Definition-creep is particularly challenging for medical writers. We must be precise in our choice of words, lest their meaning is misinterpreted—the consequences of which might be life-threatening. The same goes for sentence structure. We hold as inviolate our seventh grade English teacher's admonitions not to split infinitives, begin sentences with conjunctions, or end them with prepositions. Rules are rules.

But sometimes those rules interfere with clarity—an eternal dilemma for even the greatest writers. In responding to an editor who once tampered with his perfect prose, an irate Winston Churchill scribbled in the margin, "This is the sort of bloody nonsense up with which I will not put."

When will it end? According to Shea, never. Language evolves, and to communicate effectively, writers must adapt. Bad English becomes acceptable (if not good) English. There are exceptions to every rule, literally.

[1]Turducken is a boneless chicken stuffed into a boneless duck stuffed into a boneless turkey.

[2]A Canadian dish of French fries covered with brown gravy and cheese curds.

What's Up(!) . . . at EMA

By Wim D'Haeze, PhD

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (25 MAY 2014 THROUGH 25 JULY 2014)

The alerts listed below cover the period from May 25, 2014 through July 25, 2014. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

- None to report

REPORTS/PAPERS

- None to report

APPROVALS/REFUSALS

Compound	Indication/Use[1]	Applicant	Advice [Note]
Xultophy[a]	Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control	Novo Nordisk A/S	Positive opinion
Imbruvica[b]	Treatment of adults with relapsed or refractory mantle cell lymphoma (MCL). Treatment of adults with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.	Janssen-Cilag International NV	Positive opinion
Busulfan Fresenius Kabi[c]	Usulfan followed by cyclophosphamide (BuCy2) is indicated as conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT) in adults when the combination is considered the best available option.	Fresenius Kabi Oncology PLC	Positive opinion
Zydelig[d]	In combination with rituximab for treatment of adults with CLL who have received at least one prior therapy, or as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.	Gilead Sciences International Ltd.	Positive opinion

Accofil[e]	Indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.	Accord Healthcare Ltd.	Positive opinion
Triumeq[f]	Treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg.	ViiV Healthcare UK Limited	Positive opinion
Clopidogrel/ Acetylsalicylic acid Teva[g]	Prevention of atherothrombotic events in adults already taking both clopidogrel and acetylsalicylic acid (ASA)	Teva Pharma B.V.	Positive opinion
Daklinza[h]	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.	Bristol-Myers Squibb Pharma EEIG	Positive opinion
Vizamyl[i]	For diagnostic use only – Vizamyl is a radiopharmaceutical medicinal product indicated for Positron Emission Tomography (PET) imaging of β-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer disease and other causes of cognitive impairment.	GE Healthcare Ltd.	Positive opinion
Velphoro[j]	To reduce serum phosphorus in patients on maintenance dialyses with an acceptable safety profile based on data up to one year.	Vifor Fresenius Medical Care Renal Pharma France	Positive opinion
Abasria[k]	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.	Eli Lilly Regional Operations GmbH	Positive opinion

1. As per recommended approval

Note: “positive” or “negative” opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

• European Commission launches logo for online pharmacies to protect patients from falsified medicines.[l]
• Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014.[m]

EMA Website - What's New:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid=WC0b01ac058004d5c4 [Link]

[a].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/smops/Positive/human_smop_000714.jsp&mid=WC0b01ac058001d127 [Link]

[b].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003791/smops/Positive/human_smop_000721.jsp&mid=WC0b01ac058001d127 [Link]

[c].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002806/smops/Positive/human_smop_000713.jsp&mid=WC0b01ac058001d127 [Link]

[d].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/smops/Positive/human_smop_000720.jsp&mid=WC0b01ac058001d127 [Link]

[e].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003956/smops/Positive/human_smop_000719.jsp&mid=WC0b01ac058001d127 [Link]

[f].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002754/smops/Positive/human_smop_000704.jsp&mid=WC0b01ac058001d127 [Link]

[g].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002272/smops/Positive/human_smop_000696.jsp&mid=WC0b01ac058001d127 [Link]

[h].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/smops/Positive/human_smop_000703.jsp&mid=WC0b01ac058001d127 [Link]

[i].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002557/smops/Positive/human_smop_000698.jsp&mid=WC0b01ac058001d127 [Link]

[j].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002705/smops/Positive/human_smop_000707.jsp&mid=WC0b01ac058001d127 [Link]

[k].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002835/smops/Positive/human_smop_000706.jsp&mid=WC0b01ac058001d127 [Link]

[l].http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002130.jsp&mid=WC0b01ac058004d5c1 [Link]

[m].http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002127.jsp&mid=WC0b01ac058004d5c1 [Link]

What's Up(!) . . . at FDA

By Sally R Altman, CareFusion, San Diego

During the month of July, the FDA added several draft or revised guidances and resources to its website. And, as in previous months, the agency advised consumers not to purchase or use several weight loss or sexual enhancement products following the discovery of undeclared ingredients. In addition, the agency approved several new drugs with indications including peripheral T-cell lymphoma, consistent and severe pain, relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma, and relapsed small lymphocytic lymphoma.

Selected FDA Announcements

7-1-14	The FDA released a new guidance for industry, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.[1]
7-1-14	Bristol-Myers Squibb issued a voluntary recall of six lots of Coumadin for Injection, 5 mg single-use vials following the discovery of visible particulate matter. No product complaints had been received at the time the recall was announced.[2]
7-3-14	The FDA released a new guidance for industry, Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.[3]
7-8-14	The agency warned consumers that several weight loss products contained a hidden drug ingredient, sibutramine. Consumers were advised not to purchase or use Trim-Fast Slimming Softgel,[4] Sliming (sic) Diet,[5] Lipo 8 Burn Slim Capsules,[6] 24 Ince,[7] Lingzhi Cleansed Slim Tea,[8] or Mix Fruit Slimming.[9]
7-10-14	The FDA released three new guidances for industry, ANDA Submissions — Amendments and Easily Correctable Deficiencies Under GDUFA,[10] ANDA Submissions — Prior Approval Supplements Under GDUFA,[11] and Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act (revised draft).[12]
7-11-14	Hospira issued a voluntary recall of one lot of Lactated Ringers and 5% Dextrose Injection, USP, 1000 mL, Flexible Container based on a customer report of particulate matter. The appearance of the particulate suggested mold contamination. Further analysis determined a puncture in the container and protective wrapping caused the container to leak.[13]
7-14-14	Baxter International Inc. issued a voluntarily recall of four lots of intravenous solutions following four customer reports of particulate matter during a six-month period. The particulate was determined to be cellulosic fibers and/or plastic.[14]
7-18-14	The agency warned consumers and healthcare providers not to use sterile drugs produced by Downing Labs, also known as NuVision Pharmacy. The warning followed the discovery of unsanitary conditions resulting in contamination. Sterility failures were discovered in 19 lots of sterile drugs and endotoxin failures in three lots of drug products. A Form FDA 483 was issued for these failures on July 16.[15]
7-21-14	American Health Packaging issued a voluntary recall of two separate drug products as a result of mislabeled packaging. The recall included one lot of ibuprofen tablets erroneously labeled as oxcarbazepine tablets and one lot of oxcarbazepine tablets.[16]
7-22-14	The agency warned consumers that the sexual enhancement product O.M.G. contained a hidden drug ingredient, sildenafil. Consumers were advised not to purchase or use the product.[17]
7-23-14	Unique Pharmaceuticals issued a voluntary recall of all non-expired sterile drug products following two FDA inspections during which sterility failures, environmental contamination, and poor sterile production practices were noted.[18]
7-25-14	The FDA released a new revision of a guidance for industry, Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.[19]

Selected FDA Approvals

Drug	Indication	Company
Beleodaq™	Peripheral T-cell lymphoma[20]	Spectrum Pharmaceuticals
Targiniq ER™	Consistent pain severe enough to require continuous, long-term opioid use[21]	Purdue Pharma
Zydelig®	Relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma, and relapsed small lymphocytic lymphoma[22]	Gilead

August 2014 Advisory Committee Meetings

8-1-14	General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee[23]
8-14-14	Pulmonary-Allergy Drugs Advisory Committee[24]

August 2014 Meetings, Conferences, and Workshops

8-4/5-14	Regulation of Nonprescription Drug Products – Question and Answer Sessions[25]

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm. [Link]
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm. [Link]
- For information on current drug shortages, see http://www.accessdata.fda.gov/scripts/drugshortages [Link]
- For Orange Book drug product list additions or deletions, see http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm. [Link]

[1]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf [Link]
[2]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm403583.htm [Link]
[3]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269221.pdf [Link]
[4]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404290.htm [Link]
[5]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404293.htm [Link]
[6]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404296.htm [Link]
[7]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404299.htm [Link]
[8]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404302.htm [Link]
[9]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm404305.htm [Link]
[10]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404440.pdf [Link]
[11]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404441.pdf [Link]
[12]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404473.pdf [Link]
[13]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm404667.htm [Link]
[14]http://www.fda.gov/Safety/Recalls/ucm405469.htm [Link]
[15]http://www.fda.gov/Drugs/DrugSafety/ucm405940.htm [Link]
[16]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm406124.htm [Link]
[17]http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm406236.htm [Link]
[18]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm406419.htm [Link]
[19]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf [Link]
[20]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403929.htm [Link]
[21]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm406407.htm [Link]
[22]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm406387.htm [Link]
[23]http://www.fda.gov/advisorycommittees/calendar/ucm402768.htm [Link]
[24]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm403018.htm [Link]
[25]http://www.fda.gov/Drugs/NewsEvents/ucm406759.htm [Link]

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc.

SALAMI SLICING AND DUPLICATE PUBLICATIONS

Many authors, for example some junior faculty and post-doctoral fellows early in their career face acute pressure to "publish or perish." Often believing that fewer publications can cost them their potential tenure, and possibly even their jobs, they may resort to "salami slicing" of publications.

Salami slicing refers to dividing a single research paper into "least publishable units," with each paper reporting different findings from the same study.

> *Wasteful publication includes dividing the results in a single study into two or more papers ("salami science"); republishing the same material in successive papers; and blending data from one study with additional data to extract yet another (publication)*
>
> Edward J. Huth, MD[1]

What can a medical writer do when faced with the salami model of publishing? A medical writer can remind the author that publishing a complete and robust study has a better chance of being accepted in a higher impact journal and will garner more citations over time. The power of citations trumps the perceived value of number of publications, and more and more tenure and granting committees recognize this fact. Second, the medical writer can educate authors on the publication principles laid down by GPP2, ISMPP and AMWA, as well as the impact on public opinion if such practices become public knowledge.

Duplicate Publication is the simultaneous or subsequent reporting of essentially the same information 2 or more times in 1 or more forms of media (either print or electronic format). Duplicate reporting includes duplicate submission and may apply to both published and unpublished works.

Duplicate submission or publication is not necessarily unethical but failure to disclose the existence of duplicate articles to editors and readers (covert duplication) is unethical and may represent a violation of copyright law, pollute the literature, distort the available evidence, cause problems for researchers and for systematic reviews and meta-analyses. Exceptions are made when government health agencies determine that there is an immediate public need for a wider casting of health information.

Unfortunately, a widely accepted method of quantifying the amount of overlap or duplication does not exist. Following the recommendations of the International Committee of Medical Journal Editors (ICMJE),[2] a policy that prohibits or discourages duplicate publication does not preclude consideration of manuscripts that have been presented orally or in abstract or poster form, or included on preprint servers (eg, arXiv, bioXiv, Nature Precedings, PeerJ preprints, etc).

Secondary Publication is the subsequent republication, or simultaneous publication, of an article in 2 or more journals by *mutual consent of the journal editors.* In some cases, secondary publication can be beneficial. For example, the editors of an English-language journal and a non-English-language journal may agree to secondary publication in translated form. The ICMJE approves secondary publication if a list of strict criteria are met, including:

1. Approval is obtained from the editors of both journals

2. The secondary publication is intended for a different group of readers
3. The title of the secondary publication should indicate that it is a secondary publication

Of note, the National Library of Medicine does not consider translations to be "republications" and does not cite or index translations when the original article was published in a journal that is indexed in MEDLINE.

Editorial Policy for Preventing and Handling Allegations of Duplicate Publication. Covert duplicate publication violates the ethics of scientific publishing. When in doubt about the possibility of duplication or redundancy in articles based on the same study, authors should inform and consult the editor. All authors are required to sign an authorship criteria and responsibility statement, which includes the following declaration: Neither this manuscript nor another manuscript with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in an attachment, and copies of related manuscripts are provided.

When a manuscript previously submitted to Journal A is withdrawn for any reason, it is very important to obtain the confirmation from the editor of Journal A in writing (or email) before re-submitting that manuscript to Journal B. The reasons to withdraw may vary, but may include unusual wait times for initiation or completion of review process, or need to update and modify the manuscript in light of new data.

Duplicate Submission/Publication. If duplicate submission of a manuscript is suspected before publication, the editor should notify the author and ask for a written explanation. The editor may also choose to notify the author's institutional supervisor (eg, department chair, dean) to request assistance with acquisition of an appropriate letter from the author.

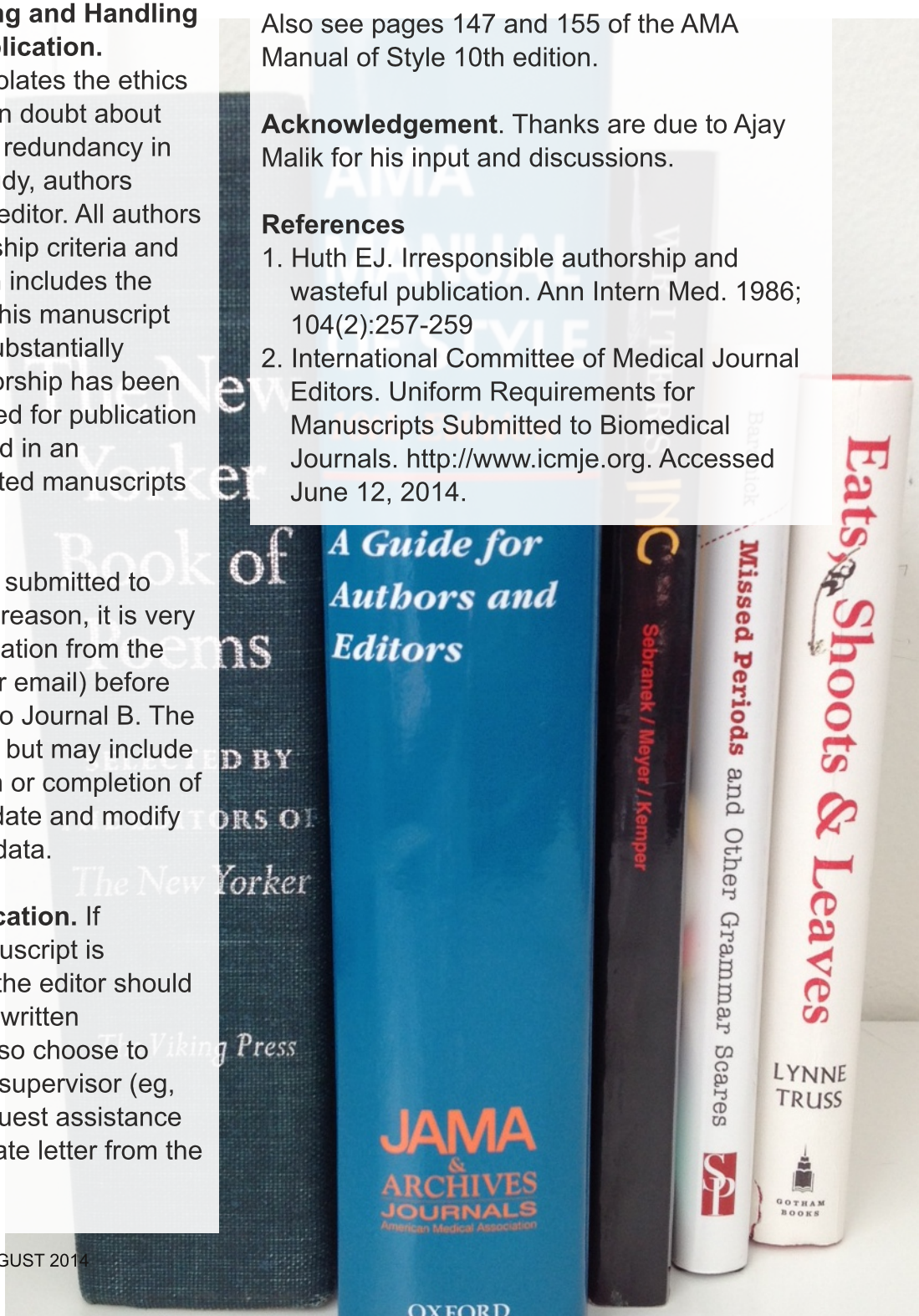
Notice of Duplicate Publication. The notice of duplicate publication should be published on a numbered editorial page and listed in the table of contents of the journal in a citable format to ensure that the notice will be indexed appropriately in literature databases. The US National Library of Medicine identifies duplicate articles in its bibliographic database by adding a publication type of "Duplicate Publication" to the record of each duplicate article.

Also see pages 147 and 155 of the AMA Manual of Style 10th edition.

Acknowledgement. Thanks are due to Ajay Malik for his input and discussions.

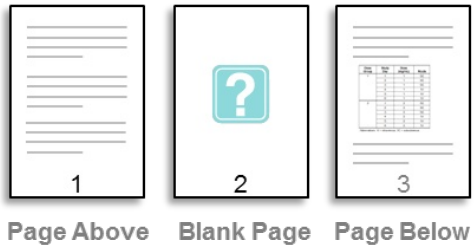
References

1. Huth EJ. Irresponsible authorship and wasteful publication. Ann Intern Med. 1986; 104(2):257-259
2. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. http://www.icmje.org. Accessed June 12, 2014.



de-MS-tifying Word: The Mystery of Blank Pages

By Susan Chang, PhD, Susan Chang Consulting

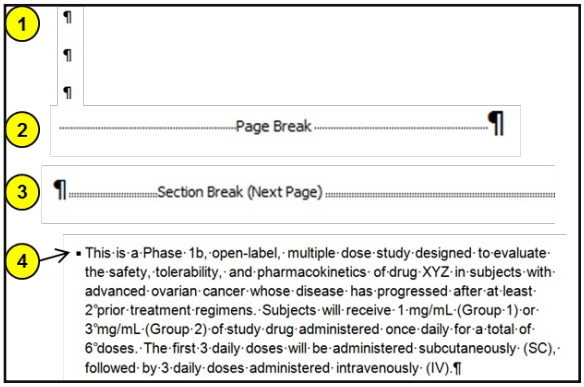


It's a common scenario: You inherit a document with a short turn-around time for revisions. Scanning through the document, you notice a major formatting problem: **BLANK PAGES!** You didn't write the document, so you must do a bit of sleuthing. Follow the clues below to solve the mystery of the blank page! Instructions are for PCs, but these concepts apply to Mac users as well.

First, always remember to turn on paragraph marks: Home tab → Paragraph group → Click " ¶ "

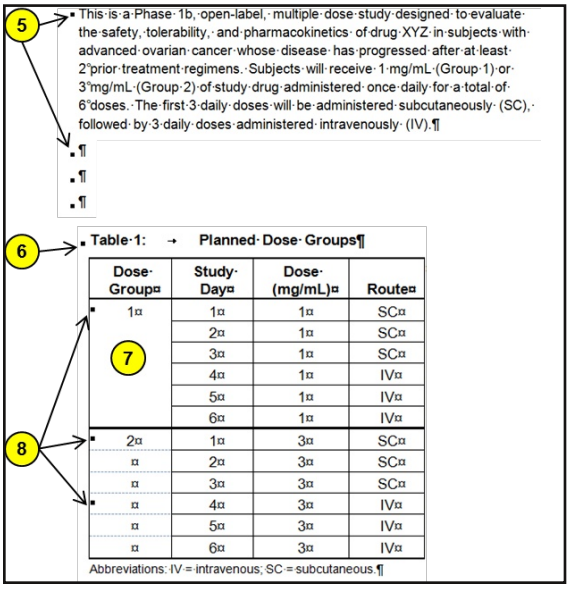
FAULTY FORMATTING – PAGE ABOVE

1) Look for a string of **hard returns**, which some writers use to push material onto the next page. Delete them!
2) Delete any manually inserted **page breaks**.
3) Look for section breaks. If there is a "next page" section break, you can delete it UNLESS the page below it has a different orientation, which requires the presence of a **section break**.
4) Explore the last paragraph of text. If you see a black box, then special formatting features are selected. Double-click the black box to open the paragraph options window. Make sure "page break before" is not selected. NOTE: Unlike section breaks and manually entered page breaks, the "**page break before**" setting is NOT visible on the page.



FAULTY FORMATTING – PAGE BELOW

5) Double-click the black box for text at the top of the page. Make sure "**keep with next**" and "**keep lines together**" are not selected. Delete **hard returns** that disrupt spacing.
6) For some text, "**keep with next**" is preferred, such as table/figure captions and section headings.
7) **Merged table rows** can also cause formatting problems. Make sure you are viewing all of the table gridlines, not just the ones with borders: Go to Table tab → Layout → **View Gridlines**. In this example, rows are merged for Group 1, but not Group 2, in the left-most column. This large cell may need to be split into multiple rows (covered in a future article).
8) Make sure table rows do not have unwanted formatting features by double-clicking black boxes in the left-most column. In this example, the "**keep with next**" option for the merged Group 1 cell could force the entire table onto a new page, potentially creating a large blank space above the table. NOTE: To keep all of Group 1 data together, modify table properties instead: Go to Table tab → Layout → Properties → Rows → Deselect "Allow row to break across page". Group 1 stays together, but it's not stuck to Group 2.



Congratulations! You have solved the mystery of the blank page.
Inspect the remaining pages to determine if any formatting features should be turned back on. To learn more about positioning elements properly in your document, refer to this past article: http://issuu.com/postscripts/docs/v3n18.
Word woes? Ideas for future issues? Email me at SKC@SusanChangConsulting.com

Safety Sentinels: Pharmacovigilance Issues and News

By Ellen Klepack, PharmD

FDA Releases Draft Guidelines for Industry on the Use of Social Media

Social media has changed the landscape on how patients, as well as health care providers, are getting information about health topics and medical products. While a number of pharmaceutical manufacturers have adopted the use of social media, risk of running into regulatory trouble coupled with little direction from FDA has led to an overall slower uptake of these types of communications compared to other business sectors. According to a study conducted by IMS Institutes for Health Informatics, 23 of the top 50 pharmaceutical manufacturers worldwide are participating in social media on Facebook, YouTube or twitter and ten use all three social networking sites for healthcare topics.[1] The report also found that Wikipedia is the single leading source of healthcare information for patients and healthcare professionals, especially for rarer diseases.[1]

The FDA began to address the topic of social media in 2009 with a public hearing that gathered information on how it could best provide guidance on the promotion of FDA-regulated medical products using the internet and social media.[2] Since that time there has been little communication from FDA about social media until the recent release of two draft guidance documents in June 2014. The first draft guidance document addresses the presentation of risk and benefit information for prescription drugs and devices using social media/internet platforms that have character space limitations.[3] The second draft guidance document addresses the correction of independent third party misinformation about prescription drugs and medical devices by industry.[4] These documents are part of an evolving series of documents produced by FDA to guide industry on appropriate use of social media and other internet platforms.

Use of Social Media with Character Space Limitations

The FDA highlights that, if a firm makes a product claim benefit on an Internet/social media platform, risk information should also be included within the same character space limitation. A platform should be reconsidered if an accurate balance of both risks and benefits cannot be achieved.[3] This would exclude reminder promotions (eg, "ask your doctor about drug X"). A benefit claim should be accurate and not misleading and, at minimum, include a product's most serious risks along with a hyperlink that is devoted only to providing more comprehensive information on product risk. A company's product webpage is not considered an acceptable hyperlink for risk information since it also contains claim benefits and other information.[3] An example of what the FDA considers an appropriate tweet would be the following:
"NoFocus for mild to moderate memory loss; may cause seizures in patients with seizure disorder www.nofocus.com/**risk**"[3]

Correction of Third Party Misinformation

Guidance on the correction of third party misinformation applies to misinformation generated by an independent third party on internet/social media platforms about a firm's product and excludes any communications for which a firm is responsible.[4] When a firm corrects misinformation, FDA suggests that the correction be relevant, non-promotional, accurate, limited to the misinformation, consistent with the product's FDA labeling, supported by sufficient evidence, posted in conjunction or in the same area on the forum as the misinformation, and include a disclosure that the person providing the corrective information is affiliated with the firm. If a firm chooses to correct any misinformation posted on a forum, the corrected portion should be clearly defined and any other instances of misinformation within that clearly defined portion, both positive and negative, should also be corrected. Firms are not expected to correct all instances of misinformation on a forum or monitor a forum or website for additional instances of misinformation once corrective information is provided. A firm may provide the corrective information directly to the author or

request that the author or site generator remove the misinformation or allow comments to be posted. The FDA will not hold a firm accountable for an independent party's subsequent actions once the corrective action is received.[4]

Sources

1. IMS Health: Pharma should make better use of social media to engage patients and improve the use of medicines [press release]. Parsippany, NJ: IMS Institute for Healthcare Informatics; January 21, 2014. http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=ebc072cc270b3410VgnVCM10000076192ca2RCRD. Accessed July 26, 2014.
2. For industry: using social media. U.S. Food and Drug Administration Web site. http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm397791.htm Accessed July 26, 2014.
3. The Office of Prescription Drug Promotion (OPDP). Guidance for industry internet/social media platforms with character space limitations—presenting risk and benefit information for prescription drugs and medical devices [draft guidance]. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf. Published June 2014. Accessed July 26, 2014.
4. The Office of Prescription Drug Promotion (OPDP). Guidance for industry internet/social media platforms: correcting independent third-party misinformation about prescription drugs and medical devices [draft guidance]. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf. Published June 2104. Accessed July 26, 2014.

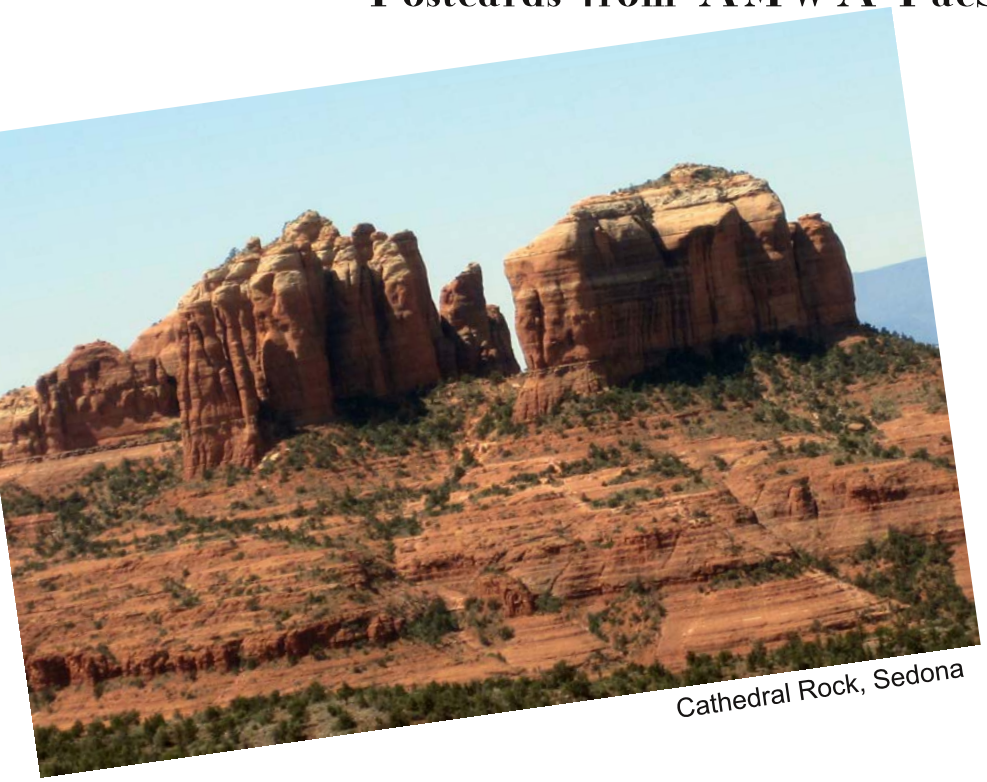
Medical Writers' Meetup at The Fish Gaslamp during DIA 2014 Meeting on June 17th

Picture courtesy of Donna Simcoe

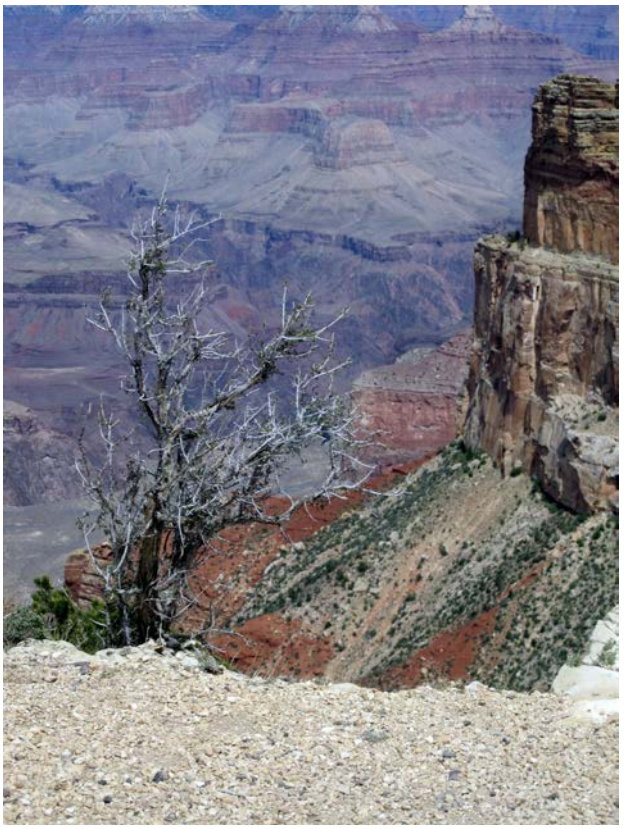
Nearly 20 attendees joined the DIA happy hour including (in alphabetical order by last name) Karin Beloussow, Valerie Breda, Susan Chang, Teresa Gallagher, Jenny Grodberg, Kai Jen, Michael Kelley, Marianne Pedersen, Donna Simcoe, Lynne Smith, Susan Vintilla-Friedman, Jennifer Weghe, Michele Wible.

Summer Travels:

Postcards from AMWA PacSW Members



Cathedral Rock, Sedona



Grand Canyon - Colors

Chapel of the Holy Cross, Sedona

Big Sky Montana Glacier Natl Park

Pictures courtese of —
Michele Mathieu (Grand Canyon and Sedona)
Deborah Brown (Big Sky)

August 2014 Job Listing

Compiled by Irene Yau, PhD, Allergan, Inc.

Principal/Senior Medical Writer
Intercept Pharmaceuticals, San Diego

Document Quality Specialist
Intercept Pharmaceuticals, San Diego

Senior Manager, Medical Writing
Ambit Biosciences, San Diego

Manager, Scientific Communications
Avanir, Aliso Viejo

Editor, Scientific/Medical
inVentive Health, Irvine

Medical Writer – Pharmaceutical
Brandkarma, Irvine

Grants and Science Writer
Council for Watershed Health, Los Angeles

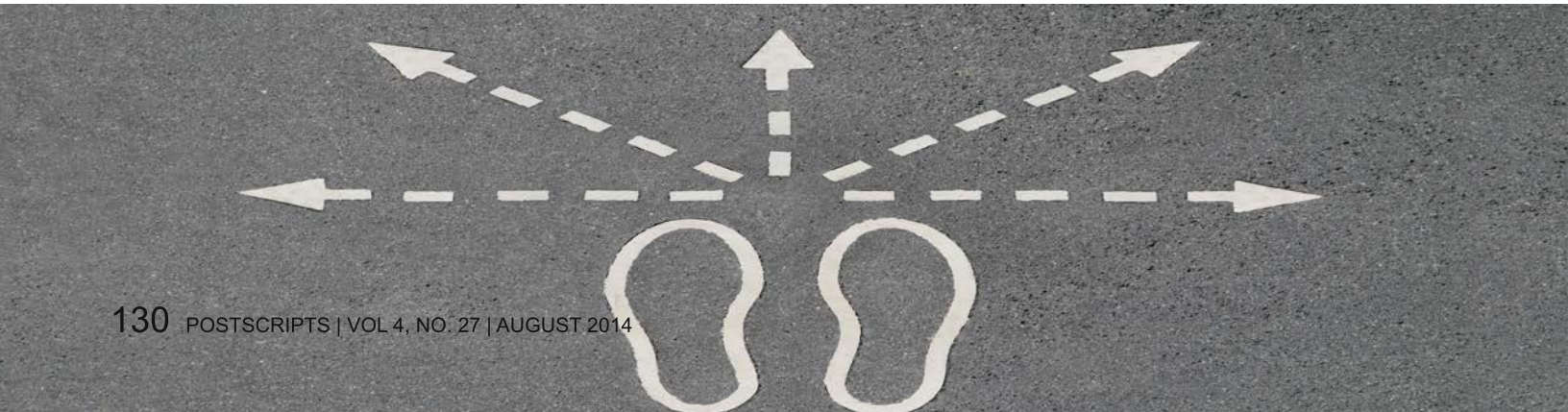
Science Writer
City of Hope, Duarte

Associate Manager, Medical Writer
Gilead, Foster City

As a reminder, complete Job Listings are available for current, interested members and are available through the following ways:

• Job openings are sent out ~monthly through the jobs mailing list
• Job listings will be posted periodically through our LinkedIn SubGroup, AMWA Pacific Southwest Chapter, so be sure to join the group

Please e-mail employment-coordinator@amwa-pacsw.org if you'd like to receive job listings or share any job leads with the group and it will be added to the job listings.



Heron (Decorative and Tole Painting)

"Heron" by Kathryn Huff.
Kathryn's work is available at Etsy, including birdhouses she painted
https://www.etsy.com/shop/HappyWood
(Picture courtesy of Michele Mathieu, AMWA PacSW member.)

"Tole painting is the folk art of decorative painting on tin and wooden utensils, objects and furniture. Typical metal objects include utensils, coffee pots, and similar household items. Wooden objects include tables, chairs, and chests, including hope chests, toyboxes and jewelry boxes." — *from Wikipedia entry on tole painting*